SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5141–5160

Adulteration, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity and quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

5141. Terramycin capsules and tablets, Meticortelone tablets, and cortisone acetate tablets. (F. D. C. No. 39628. S. Nos. 52–413 M, 52–415/8 M.)

QUANTITY: 360 *Terramycin capsules* in 1 bag, 100 *Terramycin capsules* in 1 btl., and 3 100-tablet btls. of *Terramycin tablets;* 1 85-tablet btl. of *Meticortelone tablets;* and 1 25-tablet vial of *cortisone acetate tablets* at Brooklyn, N. Y.

SHIPPED: At various times, from Groton, Conn., Bloomfield, N. J., and Philadelphia, Pa.

RESULTS OF INVESTIGATION: The *Meticortelone tablets,* after shipment, had been repackaged and relabeled by the dealer, Bedford Surgical Co., Inc., Brooklyn, N. Y., under its own labels.

LIBELED: 10–5–56, E. Dist. N. Y.

CHARGE: 501 (c)—while held for sale, the strength of the *Terramycin tablets* differed from that which they were represented to possess (the tablets contained less than the declared amount of 250 mg. of *Terramycin* per tablet); 502 (b) (2)—while held for sale, the *Terramycin capsules* (1-bag lot) and the *Terramycin tablets* failed to bear labels containing accurate statements of the quantity of contents; 502 (e) (1)—while held for sale, the label of the *Terramycin capsules* (1-bag lot) failed to bear the common or usual name of the drug; 502 (f) (1)—the labelings of all of the articles, while held for sale, failed to bear adequate directions for use, and the articles were not

entitled to any exemption from such requirement; and 503 (b) (4)—all of the articles were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the repackaged and relabeled *meticortelone tablets* were a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11–26–56. Default—destruction.

DRUG FOR VETERINARY USE

5142. Acthone gel (veterinary). (F. D. C. No. 39929. S. No. 58–623 M.)

QUANTITY: 97 5-cc. vials at Denver, Colo.

SHIPPED: Between 9–1–56 and 9–6–56, from San Francisco, Calif., by Borden Laboratory.

LABEL IN PART: (Vial) "Borden Acthone (Veterinary) Gel * * * 40 U. S. P. Corticotropin Units."

LIBELED: 1–30–57, Dist. Colo.

CHARGE: 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 3–22–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5143. Herb tonics, cold salve, and laxative tablets. (F. D. C. No. 38515. S. Nos. 14–410/1 M, 14–414 M, 14–417 M, 14–426 M, 14–470/3 M, 14–581 M, 30–148 M.)

INDICTMENT RETURNED: 3–8–56, E. Dist. Ill., against William H. Cruez, t/a East Side Herb Co., East St. Louis, Ill.

ALLEGED VIOLATION: Between 2–23–55 and 8–1–55, the defendant caused to be introduced into interstate commerce at East St. Louis, Ill., for delivery into the State of Missouri, quantities of various drugs which were labeled and misbranded as described below.

On 5–18–55, the defendant unlawfully refused entry and inspection of his establishment at East St. Louis, Ill., after having been presented by inspectors of the Food and Drug Administration with appropriate credentials and a written notice at a reasonable time, in accordance with the provisions of Section 704.

LABEL IN PART: "Herb Tonic Formula No. 1 Active Ingredients Punich, Granatum, and Pest Root"; "Herb Tonic Formula No. 3 Active Ingredients Quaking Aspen, Pride Weed, and Lucerne"; "Herb Tonic Formula No. 4 Active Ingredients Prickly Ash, Tansy Herb, Button Bush Bark and Elder Bark"; "Cold Salve" (examination showed that it contained, chiefly, petrolatum and smaller amounts of menthol and eucalyptol); and "Tablets Formula No. 556 Active Ingredients: Cascarin one-fourth grain, Aloin one-fourth grain, Podophyllin one-sixth grain, Extr. Belladonna one-eighth grain, Gingerine one-sixteenth grain. Distributed by Indiana Botanic Gardens, Hammond, Indiana."

*See also No. 5141.